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08/962,271	10/31/97	FREEMAN	04644/068001

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EXAMINER
FOSTER, J

ART UNIT
3728

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/962,271

Applicant(s)

Freeman et al.

Examiner

J. Foster

Group Art Unit

3728



☒ Responsive to communication(s) filed on Feb 22, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-51 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 1-12 and 49 is/are allowed.

☒ Claim(s) 13, 15-17, 19-48, 50, and 51 is/are rejected.

☒ Claim(s) 14 and 18 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. Claims 1-12 and 49 are allowable over the prior art of record.

2. Claims 20-51 are finally rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20-22 are functional and indefinite because there is insufficient structure recited in the claims to perform the function, "for maintaining a first said electrode in either a sealed mode ... or an unsealed mode." The term "compartment" is insufficient to support this function since compartments are not required to be openable and closable without further description. Claim 38 has a similar problem with the function, "may be exposed to the external environment by opening the envelope."

Claim 23 is functional and indefinite because there is insufficient structure recited in the claim to perform the function, "for maintaining the electrode in isolation." Claim 26 has a similar problem.

Claim 23 is also functional and indefinite because there is insufficient structure recited in the claim to perform the functions, "is removable from the compartment to expose the electrode" and "maintains the electrical connection to the electrode when the electrode is removed from the compartment."

Claim 42 is functional and indefinite because there is insufficient structure recited, regarding the location and form

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of the strain relief elements in the claim, to perform the function, "for relieving strain on the lead wires."

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 13, 15, 16, 19, 23, 24 and 46 are finally rejected under 35 U.S.C. 102(b) as being anticipated by Engel (4,539,996). In the reference of Engel, an electrode is provided at 18, and a package is defined by the combination of backing 20, strip 24 and release liner 26. The release liner is releasably adhesively attached at least to the strip 24 (see Fig. 2). Connected to the electrode 18 is an electrically conductive path/connector 16. A portion of the element 16 located under the barrier element/strip 24 may be considered to be a connector body portion of the barrier element. In addition, the tip of connector 16 may be defined as being a terminal.

Regarding a second compartment, the area between the unnumbered tabs of the backing 20, which extend beyond the strip 24, may be considered to define a second compartment within

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which the terminal end of the connector 16 resides, insofar as Applicant has claimed.

5. Claims 23-28, 45, 48 and 51 are finally rejected under 35 U.S.C. 102(e) as being anticipated by Gilman et al (5,402,884). In the reference of Gilman et al, a package is provided at 99,100, and defibrillator electrodes are provided at 128,129. The periphery of the package provides a barrier element. Extending from within the compartment of the package through the periphery of the package to the exterior environment are connectors/ connective paths/connector bodies 132,135. The portions of the connector bodies which extend through the package periphery/barrier element may be considered to be a part of the barrier element. The portions exterior to the periphery may be considered to define connectors or terminals. Inasmuch as the wire conductors and insulators of the connector bodies are round in cross section, they provides arcuate (i.e., semicircular) top and bottom portions of the connector body which are engaged by top (100) and bottom (99) walls of the package compartment.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 16, 17, 19, 43 and 44 are finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Gilman et al (5,402,884) in view of Engel (4,539,996). Although the reference of Gilman et al does not disclose how the electrode packages are opened, the reference of Engel (col. 5 lines 47-50) suggests that top and bottom walls of an electrode package may be releasably sealed in order to permit opening of the package. Accordingly, it would have been obvious in view of Engel to have made the sealed periphery of Gilman et al with a releasable seal, for the purpose of opening the package.

Although the reference of Gilman et al does not disclose sealing the top and bottom walls of the package to the upper and lower surfaces of the connector bodies 132,135, the reference of Engel (col. 5, lines 38-46; Fig. 2) suggests adhesively attaching a connector body (16) to between upper and lower walls (24,20) in an electrode package. Such adhesive attachment would inherently complete the seal of the electrode within the package. Therefore, it would have been obvious in view of Engel at 24,25 to have provided a sealing attachment between the connectors 132,135 of Gilman et al and the top and bottom walls 100,99, for the purpose of completely sealing the package.

8. Claim 50 is finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Engel (4,539,996) in view of Gilman et al (5,402,884). Although the reference of Engel does not disclose a defibrillator electrode, the reference of Gilman et al suggest providing a package for a defibrillator electrode for storing it prior to use. Accordingly, it would have been obvious in view of Gilman et al to have packaged as the

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electrode 12,18 a defibrillator electrode, for the purpose of storing it prior to use.

9. Claims 14 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 20-22 are would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. § 112.

11. Claims 29-42 and 47 would be allowable if rewritten to overcome the rejection under 35 U.S.C. § 112 and to include all of the limitations of the base claim and any intervening claims.

12. Applicant's arguments filed February 22, 1999 have been fully considered but they are not deemed to be persuasive.

Applicant has argued regarding the 112, second paragraph rejection of claims 20-22 in the first Office action that the limitation, "for maintaining a first electrode in either a sealed mode . . . or an unsealed mode" has been written by Applicant to comply with 35 U.S.C. 112, sixth paragraph "which contemplates that a functional recitation may substitute for structure." Applicant further argues that 35 U.S.C. 112, sixth paragraph provides for claiming function without structure to support it.

The examiner disagrees. 35 U.S.C. 112, sixth paragraph permits claimed structure to be claimed as "means" together with a specified function which is performed by the means, and the

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term "means" shall be construed to describe all the corresponding structure as it is described in the specification or an equivalent to that structure which performs that function. Inasmuch as Applicant employs the term "compartment" and not "means", Applicant's limitation cannot comply with the 35 U.S.C. 112, sixth paragraph format for a limitation because the term "compartment" is broader than a compartment having a seal adapted to be released and therefore must be considered to be less comprehensive than the corresponding structure described in the specification for the compartment.

Moreover, Applicant's limitation, "compartment" goes against the stricture against further reciting the structure which performs the function. See Cole v. Kimberly-Clark Corp., 41 USPQ2d 1001, 1006 (CAFC 1996). The term "compartment" is typically defined to mean a *separate section*, which definition is more descriptive than which is permitted by 35 U.S.C. 112, sixth paragraph.

Insofar as Applicant's limitation does not comply with 35 U.S.C. 112, sixth paragraph, the term "compartment" must be examined with respect to its broadest reasonable interpretation, a *separate section*, which lacks sufficient structure to perform the sealing function. This causes the claim to be indefinite because it is unclear and confusing whether the unclaimed additional structure that would be required to perform the sealing function is being positively recited in the claim. In other words, it makes it unclear what structure is covered by the claim.

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The other rejected limitations suffer from the same kind of problem since, in each case, Applicant does not employ the term "means" together with the function or recite sufficient structure to perform the related function recited in the claim.

Regarding the art rejections, Applicant has argued that the tab 16 of Engel ('996) is not a connector since a "connector" is something which allows an electrical connection to be made. Applicant makes the same argument for the wires of Gilman et al ('884). The examiner responds that the element 16 is capable of allowing an electrical connection to be made, such as by attaching an electrical circuit by alligator clip thereto or even welding a wire thereto. The same goes for the wires of Gilman et al.

It is ironic that Applicant has argued that tab 16 is not a connector within the "normal usage in the field", when the Engel reference itself (which is in the field) describes the tab as a "connector tab" (For example, see column 5, lines 19-20).

Applicant has argued, regarding rejections over Engel, that Applicant's disclosed connector has terminals. However, since Applicant does not claim any terminals in the claims rejected by Engel, the argument is unpersuasive. Limitations argued by Applicant that are not present in the claim will not be read thereinto. In re Prater, 415 F.2d 1393, 1405, 162 USPQ 541, 550 (CCPA 1969).

Applicant provides the same argument regarding *terminals* against the rejections of Gilman et al (apparently pertinent to limitation found in Applicant's claim 27). Applicant argues, in the examiner's opinion wrongly, that wires 132,135 of Gilman et al are not connectors because they are not capable of making and

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breaking an electrical connection. This argument is not believed to be practical nor sound. The wires of Gilman et al provide an electrical connection. And first ends of the wires, i.e., terminals thereof, are electrically connected to the conductive gel layers of the defibrillator electrodes so as to provide an electrically conductive path. Moreover, wires with first ends must have second ends since it is impossible to make an infinite length wire and since for wires to provide an electrical current, as with a defibrillator, they must be connected/connectible to a power source to necessarily provide the required high currents. Finally, as to Applicant's argument, rightly or wrongly, that all terminal connections must be able to be broken, the examiner asserts that ultimately all connections to wires are capable of being broken at or about the wire end, with some being more easily breakable than others.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. To insure prompt handling of correspondence after final rejection, it should be addressed **BOX AF**.

For contacting the PTO by phone, the following contact numbers may be used:

For tracking of papers and association of papers with cases --
Clerical supervisors:

Ebony Smith (703)305-3570

For matters regarding examination -- Examiner:

Jim Foster (703)308-1505

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For faxing of correspondence:

Draft amendments only- (703)308-7769

(Examiner should be notified of fax)

Formal correspondence- (703)305-3579 or 305-3580

For any petitions:

Before the Examiner . (703)308-1505

Before the Director . (703)308-3872

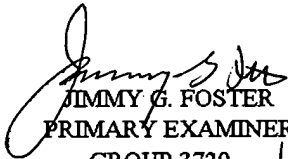
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May 22, 1999